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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,108	07/21/2000	SUSAN ANN CHARMAN	13627	9165

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03/11/2003

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EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 03/11/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/555,108

Applicant(s)
Charman et al

Examiner
Karen Canella

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1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6-18, 20-26, 28-30, 32, and 34-55 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 6-15, 20-26, 28-30, 32, 34-44, and 46-55 is/are rejected.
- 7) ☒ Claim(s) 2, 3, 16-18, and 45 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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Response to Amendment

1. Claims 1-3, 6-18, 20-26, 28-30, 32, 34-55 are under consideration.
2. After review and reconsideration, the finality of the last Office action is withdrawn.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections Withdrawn

4. The rejection of claim 6 under 112, second paragraph is withdrawn in light of applicants arguments
5. The rejection of claims 1-3, 6-13, 15, 16, 20-26, 28, 29, 32, 34-40, 47, 50 and 51 as being anticipated by Patterson et al (U.S. 6,156,729) is withdrawn in light of applicants arguments.
6. The rejection of claims 1-3, 6-18, 20-26, 28-30, 32, 34-55 as being unpatentable over Patterson et al (U.S. 6,156,729) in view of Cleland (Crit Rev Therapeutic Drug Carrier Systems, 1993, Vol. 10, pp. 307-377), is withdrawn in light of applicants arguments.

New Grounds of Rejection

7. Claims 2, 3, 16, 17, 18 and 45 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend upon claims which are not preceding claims, i.e. claims 2, 3, 16 and 17. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1, 6-15, 20-26, 28-30, 32, 34-44 and 46-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague and indefinite in the

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recitation of leukemia inhibitory factor as the sole means of identifying a constituent of the claimed compositions. The use of laboratory designations only to identify a particular inhibitory factor renders the claims indefinite because different laboratories may use the same laboratory designations to define completely distinct inhibitory factors. Furthermore, the art recognizes LIF as a synonym for at least nine different factors (see abstract of Van Vlasselaer et al, Prog Growth Factor Res, 1992, Vol. 4, pp. 337-353) and it is unclear if the claims are limited to one particular LIF or encompass all known LIFs in humans and animal species as well as LIFs yet to be discovered. Amendment of the claims to include a unique identifier, such as a sequence identifier, is suggested.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1, 6-15, 20-26, 28-30, 32, 34-44, and 46-55 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are drawn to compositions comprising leukemia inhibitory factor, or a derivative or homolog thereof.

The specification defines leukemia inhibitory factor as synthetic, recombinant or purified naturally occurring LIF from animal or avian species. Thus, the specification does not provide any particular definition for leukemia inhibitory factor. In this circumstance, leukemia inhibitory factor will take its definition from the ordinary usage in the art. The art recognizes LIF as a synonym for at least nine different factors defined on the basis of their effect on a variety of cell types including lymphomas, liver cells, embryonic stem cells and carcinoma cells (see abstract of

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Van Vlasselaer et al, *Prog Growth Factor Res*, 1992, Vol. 4, pp. 337-353). More recently, it has been recognized that LIFs are structurally related to cytokines such as Il-6, oncostatin M, ciliary neurotrophic factor, Il-11 and cardotrophin-1, and in addition have redundant activities with said cytokines (see abstract of Taupin et al, *Int Rev Immunol*, 1998, Vol. 16, pp. 397-426). Thus, LIFs are part of a family of cytokines, and the claimed derivatives homologs or functional equivalents thereof read on Il-6, oncostatin M, ciliary neurotrophic factor, Il-11 and cardotrophin-1 and other members of the family as yet to be discovered, as well as LIFs from other species, allelic variants, mutants and LIFs as yet to be discovered. It is noted that the term LIF is defined by the specification as including all derivative and homologs of LIFs as well as "synthetic recombinant or purified naturally occurring LIF from animal or avian species. Thus, the claims are drawn to a genus of proteins. Furthermore, said genus is highly variant because neither the specification nor the claims place any limit on the number of amino acid substitutions, deletions, insertions and/or additions that may be made to LIF within the scope of homologs or functional equivalents thereof. Further, the ordinary useage of the term "derivative" encompasses any possible chemical modification as well as multiple chemical modifications. It can be concluded that the specification fails to teach the common structural attributes of members of the claimed genus. The specification states on page 4 that derivatives, homologs, mimetics and analogues include parts, fragments or portions of LIF which are functionally active or which otherwise have a useful biological activity. In light of the fact that any fragment of any protein has a useful biological activity in that it can be used to raise an antibody, the definition in the specification fails to place a limitation on the specific functional characteristic of the claimed genus, and the art teaches that the LIF proteins have pleiotropic effects, and are active on a wide variety of cell or tissue types (Van Vlasselaer et al, *ibid*, and the abstract of Hilton et al, *Journal of Cell Biochemistry*, 1991, Vol. 46, pp. 21-26). Thus, the limitation of "functional equivalents" or homologue does not signify a specific functional characteristic that one of skill in the art could use to determine if a given protein was excluded or included within the claimed genus. Since the

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disclosure fails to identify common structural and functional attributes of the members of the claimed genus, and because the genus is highly variant, the recitation of LIF is insufficient to describe the genus. One of skill in the art would conclude that the disclosure fails to provide a representative number of species to describe the claimed genus. Therefore applicant was not in possession of the claimed genus at the time of filing.

12. All other rejections and objections as stated in Paper No. 14 are withdrawn.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

February 27, 2003


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